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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,538	01/23/2001	Yingjian Wang	17281/00002	2993

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EXAMINER	
CELSA, BENNETT M	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 04/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/767,538	WANG ET AL.	
	Examiner	Art Unit	
	Bennett Celsa	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2002*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *1-36,40-42 and 50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-39 and 43-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendment dated 2/5/02 is hereby acknowledged.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Claims

Claims 1-50 are currently pending.

Claims 37-39 and 43-49 are under consideration.

Claims 1-36, 40-42 and 50 are withdrawn from consideration as being directed to a nonelected invention.

Election/Restrictions

Applicant's election with traverse of Group III (claims 37-49) in Paper No. 5 is acknowledged. Applicant's further election of

a. DNA (as specific type of reagent); and

b. Supports (claims 43-45; as barrier species

The requirement (as modified above) was previously made FINAL.

This application contains claims ***1-36, 40-42 and 50*** drawn to a nonelected invention. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Withdrawn Objection (s) and/or Rejection (s)

Applicant's amendment has overcome the objection of claims 37 (line 1: "twp").

Applicant's amendment has overcome the indefinite rejection of claim 46 for lack of antecedent basis.

Outstanding Objection (s) and/or Rejection (s)

Claims 37-39, 43-44 and 47-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Chin et al. US Pat. No. 6,197,599 (3/01: filed 7/98).

Present claim 37 is drawn to a method for contacting two or more "reagents" with "one or more biological targets" comprising:

1. providing a "reagent" array (e.g. 2 or more reagents at predefined separate locales by barrier);

2. providing one more "biological targets" immobilized on a target support;

3. designating (and corresponding) an "address" for each reagent locale and a corresponding address for a biologic target;

4. contacting reagents to corresponding targets whereby some or all of each reagent is "transferred" to said biologic target.

Chin et al. teach both a method and apparatus for making (micro)arrays comprising "two or more reagents" (e.g. 2 or more "agents" including proteins and "small molecules": see col. 3) and "one or more barriers ... wherein each portion is maintained at predefined positions ... portions is adapted to be brought into contact with one or more predefined biological targets" in which the "barrier" comprises a "solid support" (e.g. glass/plastic plates or membranes including PVDF, nylon etc. : see e.g.

col. 4). The Chin et al. polymer arrays are then subjected to assay (e.g. see examples, especially examples 3 and 4) which comprises the correspondence to and contacting of immobilized addressable "biological target(s)" (e.g. polypeptides) to the predefined reagent portions (e.g. see examples 3 and 4; col. 7, lines 60-65; figures 1-4; and patent claims). It is noted that the reference teaches "seeding and adhering biological targets" of claim 47 where the targets *are non-cellular* (e.g. protein) since contacting of the reference reagent to its target effectuate "seeding and adhering" within the scope of the presently claimed invention. Similarly, the reference teaching of applying (in any manner) the reagent to its target meets "the step of applying one or more conditions" (where conditions are open-ended: e.g. include physical/chemical/mechanical and other parameters) since such conditions would include the application but the temperature and/or physical parameters exercised by the reference procedure.

Discussion

Applicant's arguments directed to the above rejection, which was modified in response to applicant's amendment, were considered but deemed nonpersuasive for the following reasons.

Applicant argues that "similar to Shalon et al's arrays" the Chin targets (reagents?) remain on the array at all times throughout the assay in contrast to the subject invention in which at least a portion of the reagents **dissociate** from the array to the target" (emphasis provided). .

This argument was considered but deemed nonpersuasive for the following reasons.

First applicant's argument is not commensurate in scope to the presently claimed invention which does not claim dissociation of the reagent from the array to the target. The claim (e.g see step 4 above) recites that some or all of each reagent is "transferred" to said biologic target. In this respect there is no specification definition of the term "transferred" in the present context and as such would read on a reagent proteins interacting and/or adhering to its target. IN fact, as pointed out in the rejection above, this interpretation is consistent with present claim 47 in which the term "transferred" "comprises the step of, seeding and adhering one or more said biologic targets on said biologic targets' corresponding predefined reagent portions"

Accordingly, the above rejection, as modified, is hereby maintained.

Claims 37-39 and 43-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Sabatini US Pat. No. 6,544,790 (4/03: filed 9/99).

Present claim 37 is drawn to a method for contacting two or more "reagents" with "one or more biological targets" comprising:

1. providing a "reagent" array (e.g. 2 or more reagents at predefined separate locales by barrier);

2. providing one more "biological targets" immobilized on a target support;

3. designating (and corresponding) an "address" for each reagent locale and a corresponding address for a biologic target;

4. contacting reagents to corresponding targets whereby some or all of each reagent is "transferred" to said biologic target.

Sabatini teaches both a method and apparatus for making (micro)arrays comprising "two or more reagents" (e.g. DNA/RNA: bottom of col. 1 to top of col. 2) and "one or more barriers ... wherein each portion is maintained at predefined positions ... portions is adapted to be brought into contact with one or more predefined biological targets" in which the "barrier" comprises a "solid support" (e.g. any "flat surface" including slides made of glass which can be polymer coated e.g. with polylysine; or bottom of wells in multi-welled plates: see col. 2). The Sabatini reference further teaches "providing one or more biological targets" which include cells grown on "growth supports" and/or applied (seeded/adhered) to the DNA/RNA reagent while employing growth medium (DMEM) (e.g. see col. 4). The Sabatini reference further teaches the making of immobilized addressable targets (e.g. cells) within the scope of the presently claimed invention (e.g. ... "distinct and defined areas of a lawn of cells": see col. 14, especially lines 13-16 and figures especially fig. 4a) for transfection with arrayed DNA (e.g. transfer of reagent DNA to target cell). The Sabatini reference method further teaches the use of any transfection technique (e.g. see col. 1, especially lines 30-40) including electroporation (e.g. electric pulse) as a condition to facilitate transfer (e.g. transfection) of the DNA/RNA into the target cell (s). See also figures and patent claims.

Discussion

Applicant's arguments directed to the above rejection, which was modified in response to applicant's amendment, were considered but deemed nonpersuasive for the following reasons.

Applicant first argues that "Sabatini does not disclose providing one or more biological targets on a target support".

This argument was considered but deemed nonpersuasive for the following reasons. As pointed out in the rejection above, the Sabatini reference clearly teaches the formation of immobilized (e.g. lawns of cells) cells for transfection.

Applicant further argues that "Sabatini's eukaryotic cells adhere to the array in contrast to the subject invention in which at least a portion of the reagents **dissociate** from the array to the target" (emphasis provided). .

This argument was considered but deemed nonpersuasive for the following reasons.

First applicant's argument is not commensurate in scope to the presently claimed invention which does not claim dissociation of the reagent from the array to the target. The claim (e.g see step 4 above) recites that some or all of each reagent is "transferred" to said biologic target. In this respect there is no specification definition of the term "transferred" in the present context and as such would read on a reagent proteins interacting and/or adhering to its target. IN fact, as pointed out in the rejection above, this interpretation is consistent with present claim 47 in which the term "transferred" "comprises the step of, seeding and adhering one or more said biologic targets on said biologic targets' corresponding predefined reagent portions

Secondly, the reference explicitly teaches "transfection" of the DNA reagent into the target cell which reads on "transfer" as presently claimed.

Accordingly, the above rejection, as modified, is hereby maintained.

New Objection (s) and/or Rejection (s)

Claim 37-39, 43-45 and 47-48 rejected under 35 USC 102 as anticipated or alternatively under 35 U.S.C. 103(a) as being unpatentable over Shalon et al. WO 95/35505 (12/95).

Present claim 37 is drawn to a method for contacting two or more "reagents" with "one or more biological targets" comprising:

1. providing a "reagent" array (e.g. 2 or more reagents at predefined separate locales by barrier);

2. providing one more "biological targets" immobilized on a target support;

3. designating (and corresponding) an "address" for each reagent locale and a corresponding address for a biologic target;

4. contacting reagents to corresponding targets whereby some or all of each reagent is "transferred" to said biologic target.

Shalon et al. teaches both a method and apparatus for making micro arrays comprising "two or more reagents" (e.g. 2 or more polynucleotides or polypeptides) and "one or more barriers ... wherein each portion is maintained at predefined positions ... portions is adapted to be brought into contact with one or more predefined biological targets" in which the "barrier" comprises a "solid support" (e.g. uncoated or glass coated with a polymer i.e. polylysine and grids e.g. addresses) . See e.g. abstract; pages 7-8; claims and figures (especially fig. 3).

The Shalon et al. polymer arrays are then subjected to assay which comprises the correspondence to and contacting of "biological target(s)" (e.g.

polynulcleotides/polypeptides) to the predefined reagent portions (e.g. see figures, especially fig. 5-12). It is noted that the reference teaches "seeding and adhering biological targets" of claim 47 where the targets *are non-cellular* (e.g. DNA/protein) since contacting of the reference reagent to its target effectuate "seeding and adhering" within the scope of the presently claimed invention. Similarly, the reference teaching of applying (in any manner) the reagent to its target meets "the step of applying one or more conditions" (where conditions are open-ended: e.g. include physical/chemical/mechanical and other parameters) since such conditions would include not only the application but the temperature and/or physical parameters exercised by the reference procedure.

The Shalon et al. reference differs from the presently claimed invention by failing to explicitly teach "designating an address to each of said biological targets immobilized on a target support".

Initially, it is noted that there are only two possibilities: the use of non-immobilized targets or the use of immobilized target arrays (e.g. addressable target arrays)

However, Shalon clearly teaches forming "addressable" microarrays (and the benefits thereof: see e.g. pages 1-3: including automated, addressable, less detection step interference) of biological samples on a support in which the samples comprise "reagents" which include biopolymers (e.g. see definition page 12; polynucleotides/polypeptides). E.g. see abstract; pages 5-7.

Additionally, Shalon teaches that for "large scale screening assays" (e.g. in medical diagnositics, drug discovery, molecular biology, immunology and toxicology) in

addition to the genetic (e.g. DNA) applications dealing with hybridization, "arrays of **whole cells**, peptides, enzymes, **antibodies**, antigens, receptors, ligands, phospholipids, polymers, drug cogener preparations or chemical substances can be fabricated by the means described in this invention". See e.g. bottom of page 31-top of page 32. Accordingly, the reference EXPLICITLY teaches forming "addressable arrays" of TARGETS (e..g. whole cells/ antibodies etc.) which would correspond to the presently claimed invention (as amended) directed to designating an address to each of said biological targets immobilized on a target support". Accordingly, selecting one of only two alternatives (e.g. immobilized vs. non-immobilized target) would either be anticipated by the Shalon reference or alternatively obvious to one of ordinary skill in the art in order to more effectively perform "large screening assays" as taught by the reference.

Discussion

Applicant's arguments directed to the above rejection, which was modified in response to applicant's amendment, were considered but deemed nonpersuasive for the following reasons.

Applicant first argues that Shalon discloses a method and apparatus for making microarrays but fails to disclose the claim 37 method of bringing two or more reagents in contact with one or more biological targets.

This argument was considered but deemed nonpersuasive for the following reasons.

Shalon clearly discloses (e.g see pages 29-32 and examples) the use of its (DNA) microarrays in assays (e.g. hybridization) for bringing into contact with one or more biological targets (e.g. target DNA).

Applicant further argues that "Shalon's et al.'s immobilized reagent remain on the array at all times throughout the assay in contrast to the subject invention in which at least a portion of the reagents **dissociate** from the array to the target" (emphasis provided). .

This argument was considered but deemed nonpersuasive for the following reasons.

First applicant's argument is not commensurate in scope to the presently claimed invention which does not claim dissociation of the reagent from the array to the target.

The claim (e.g see step 4 above) recites that some or all of each reagent is "transferred" to said biologic target. In this respect there is no specification definition of the term "transferred" in the present context and as such would read on a DNA reagent hybridizing (e.g. adhering) to its target strand which is taught by the reference. IN fact, as pointed out in the rejection above, this interpretation is consistent with present claim 47 in which the term "transferred" "comprises the step of, seeding and adhering one or more said biologic targets on said biologic targets' corresponding predefined reagent portions"

Applicant further argues that Shalon et al. fails to teach "designating an address to each of the biological targets".

This argument is not persuasive for the reasons provided in the above-modified rejection. Namely the Shalon et al. reference provides explicit motivation to utilize its spacially addressable microarray to form immobilized addressable targets in order to more efficiently perform large assay methods addressing such targets (e.g. cells/antibodies).

Accordingly, the above modified rejection is hereby maintained.

Relevant Documents

1. Blumberg US 6,274,321.

2. 60/154,737 (Sabatini, filed 9/17/99).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Future Correspondences

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-273-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639

BC
April 21, 2004